BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the proposed amendment of ARM 24.174.301, 24.174.501, 24.174.604, 24.174.711, 24.174.1411, and 24.174.2106, pertaining to definitions, foreign graduates, preceptor requirements, technician ratio and pharmacy security requirements, the proposed adoption of new rule I, licensing, new rule II, personnel, new rule III, absence of pharmacist, new new rule IV, use of emergency drug kits, new rule IV, drug distribution, new rule V, pharmacist responsibility, new rule VI, sterile products, new rule VII, return of medication from long term care facilities, and new rule VIII, pharmacist meal/rest breaks, and the proposed repeal of ARM 24.174.302, health care facility definition, 24.174.810, class I facility, 24.174.811, class II facility and 24.174.812, class III facility	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT, ADOPTION AND REPEAL

TO: All Concerned Persons

1. On August 2, 2002, at 10:00 a.m., a public hearing will be held in the Business Standards Division conference room 471-473, 4th Floor, 301 South Park Avenue, Helena, Montana to consider the proposed amendments, adoption and repeal of the above-stated rules.

2. The Department of Labor and Industry will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the Board of Pharmacy no later than 5:00 p.m., on July 29, 2002, to advise us of the nature of the accommodation that you need. Please contact Becky Deschamps, Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513; telephone (406) 841-2355; Montana Relay 1-800-253-4091; TDD (406) 444-2978; facsimile (406) 841-2343; e-mail dlibsdpha@state.mt.us.

3. The rules proposed to be amended provide as follows: (stricken matter interlined, new matter underlined)

24.174.301 DEFINTIONS (1) remains the same, but is renumbered (6).

(2) remains the same, but is renumbered (7).

(3) remains the same, but is renumbered (10).

(4) remains the same, but is renumbered (18).

(5) remains the same, but is renumbered (21).

(6) remains the same, but is renumbered (23).

(7) remains the same, but is renumbered (26).

(1) "Biological safety cabinet" means a contained unit suitable for the preparation of low to moderate risk agents and where there is a need for protection of the product, personnel and environment according to national sanitation foundation standard 49.

(2) "Class IV facility" means a family planning center under the administrative jurisdiction of the maternal and child health services bureau, department of public health and human services, and which has a Class IV facility pharmacy registered and licensed by the board.

(3) "Class 100 environment" means an atmospheric environment which contains fewer than 100 particles 0.5 microns in diameter per cubic foot of air, according to federal standard 209E.

(4) "Clean room" means a room in which the concentration of airborne particles is controlled.

(5) "Cytotoxic" means a pharmaceutical agent capable of killing living cells.

(8) "Drug order" means a written order issued by an authorized practitioner, or a verbal order promptly reduced to writing and later signed by an authorized practitioner, for the compounding and dispensing of a drug or device to be administered to patients within the facility.

(9) "Drug room" means a secure, lockable temperature-controlled location within a facility that does not have an institutional pharmacy and which contains drugs and devices for administration to patients within the facility pursuant to a valid drug order.

(11) "Emergency drug cart" or "crash cart" means a secure lockable cart containing drugs and devices necessary to meet the immediate therapeutic needs of inpatients or outpatients and which cannot be obtained from any other authorized source in sufficient time to prevent risk or harm or death to patients.

(12) "Emergency kits" are sealed kits containing those drugs which may be required to meet the immediate therapeutic needs of patients within an institution not having an in-house pharmacy, and which would not be available from any other authorized source in sufficient time to prevent risk or harm or death to patients.

(13) "Facility" means an ambulatory surgical facility, a hospital and/or long term facility, or a home infusion facility.

(14) "Floor stock" means prescription drugs not labeled for a specific patient which are maintained at a nursing station or other hospital department other than the pharmacy, and which are administered to patients within the facility pursuant to a valid drug order. Floor stock shall be maintained in a secure manner pursuant to written policies and procedures, which shall include but not be limited to automated dispensing devices.

(15) "Formulary" means a current compilation of pharmaceuticals authorized for use within the institution by representatives of the medical staff and pharmacy department.

(16) "Home infusion facility" means a facility where parenteral solutions are compounded and distributed to outpatients pursuant to a valid prescription or drug order.

(17) "Institutional pharmacy" means that physical portion of an institutional facility where drugs, devices and other material used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded and distributed to other health care professionals for administration to patients within or outside the facility, and pharmaceutical care is provided; and which is registered with the Montana board of pharmacy.

(19) "Long term care facility" has the same meaning as provided in 50-5-101, MCA, and means a facility or part of a facility that provides skilled nursing care, residential care, intermediate nursing care, or intermediate developmental disability care to a total of two or more individuals or that provides personal care.

(20) "Night cabinet" means a secure locked cabinet or other enclosure located outside the pharmacy, containing drugs which authorized personnel may access in the absence of a pharmacist.

(22) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of skin.

(24) "Provisional pharmacy" means a pharmacy licensed by the Montana board of pharmacy and includes but is not limited to federally qualified health centers as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

(25) "Qualified patients" means patients who are uninsured, indigent or have insufficient funds to obtain needed prescription drugs.

(27) "Sterile pharmaceutical" means any dosage form containing no viable microorganisms, including but not limited to parenterals and ophthalmics.

AUTH: 37-7-201, MCA
IMP: 37-7-102, 37-7-201, 37-7-301, 37-7-406, MCA

REASON: The Board has determined that there is reasonable necessity to amend ARM 24.174.301 to include updated definitions that reflect current institutional pharmacy practices, and to provide definitions that are used in the proposed NEW RULES.

24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST (1) and (2) remain the same.

(3) An interview by the board of pharmacy or its designee, the test of English as a foreign language, test of spoken English and the foreign pharmacy graduate equivalency exam provided by the national association of boards of pharmacy will be required for pharmacy graduates from outside the 50 states, the District of Columbia or Puerto Rico, who seek certification of educational equivalency in order to sit for the North American pharmacist licensure examination. A scaled score of 75 or greater will be the passing score for this examination. A candidate who does not attain this score may retake the examination after a 91 day waiting period.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-302, MCA

REASON: The Board has determined there is reasonable necessity to amend ARM 24.174.501 to assure an adequate supply of well-trained pharmacists able to practice in Montana, especially in under-served areas of the state. In order to maintain that supply, the Board finds it necessary to amend the rule to permit appropriately qualified pharmacists who were trained other than in the United States, who have appropriate English language skills, to be able to sit for the examination for licensure in Montana.

24.174.604 PRECEPTOR REQUIREMENTS (1) through (1)(b) remain the same.

(c) be engaged in ~~full time~~ active practice while acting as preceptor;

(d) through (3) remain the same.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The Board has determined there is reasonable necessity to amend ARM 24.174.604 by removing certain practice requirements, in order to maintain an adequate pool of qualified preceptors.

24.174.711 RATIO OF PHARMACY TECHNICIANS TO SUPERVISING PHARMACISTS (1) through (4) remain the same.

(5) If a pharmacy desires more than one technician to work under the supervision, direction and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist-in-charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to the following:

(a) design and equipment;

(b) information systems;

(c) work flow; and

(d) quality assurance procedures.

(6) The board shall grant approval of a pharmacy service plan only when the board is satisfied that the provision of pharmaceutical care by the pharmacy will be enhanced by the increased use of technicians.

(7) No pharmacy shall modify a board approved pharmacy service plan without the prior written approval of the board.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA

REASON: The Board has determined that there is reasonable necessity to amend ARM 24.174.711 to identify the factors the Board will consider when presented with a ratio variance request. The Board has recently been faced with requests for ratio variances.

24.174.1411 SECURITY REQUIREMENTS (1) through (3) remain the same.

(4) The registrant shall notify law enforcement officials of any theft or loss of any dangerous drug promptly upon discovery of such theft or loss and forward a copy of that agency's report to the board within 30 days.

AUTH: 50-32-103, MCA
IMP: 50-32-106, MCA

REASON: The Board has determined that there is reasonable necessity to amend ARM 24.174.1411 to require that in addition to reporting loss or theft of dangerous drugs to the Board, the pharmacy must also report the loss or theft to local law enforcement officials, as part of the protection of the public health and safety. In addition, the Board believes that requiring the reporting of the loss or theft of dangerous drugs will substantiate those matters, and will help prevent false claims of loss or theft that might be used to disguise improper diversion of those drugs.

24.174.2106 REGISTERED PHARMACIST CONTINUING EDUCATION - APPROVED PROGRAMS (1) Continuing education programs sponsored by providers that are approved by the following organizations will automatically qualify for continuing education credit:

(i) the American council on pharmaceutical education (ACPE) ~~will automatically qualify for continuing education credit~~ ;

(ii) programs that have been approved for continuing medical education (CME) by a state board of medical examiners or its equivalent; or

(iii) the American board of medical specialties.

(2) and (3) remain the same.

AUTH: 37-1-319, MCA
IMP: 37-1-306, MCA

REASON: The Board has determined that there is reasonable necessity to amend ARM 24.174.2106 to expand the list of approved continuing education sponsors in order to help ensure that licensees have access to flexible, cost-effective, and geographically accessible continuing education programs, as required by 37-1-306, MCA.

4. The proposed new rules provide as follows:

NEW RULE I LICENSING OF INSTITUTIONAL PHARMACIES

(1) All institutional pharmacies shall register annually with the board of pharmacy on a form or an electronic representation of a form provided by the board. Institutional pharmacies providing outpatient pharmacy services shall register the outpatient pharmacy separately.

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-321, MCA

REASON: The Board has determined there is reasonable necessity to adopt proposed NEW RULE I both to clarify the requirements for licensing of institutional pharmacies as well as to provide for the newly available option of on-line, electronic registration. NEW RULES I through VII and the proposed repeals generally revise and clarify the process and manner in which institutional pharmacies are licensed, in response to changes within the health care delivery system.

NEW RULE II PERSONNEL (1) Each institutional pharmacy must be directed by a pharmacist-in-charge who is licensed to engage in the practice of pharmacy in the state of Montana and who is responsible for the storage, compounding, repackaging, dispensing and distribution of drugs within the facility. Depending upon the needs of the facility, pharmacy services may be provided on a full or part-time basis, with emergency service provided at all times. Contractual providers of pharmacy services shall meet the same requirements as pharmacies located within the institution.

(2) Registered pharmacy technicians or technicians-in-training may be utilized pursuant to the written policies and procedures of the institutional pharmacy. Exemptions to established ratios as defined in ARM 24.174.711 may be granted with board approval.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, MCA

REASON: The Board has determined that there is reasonable necessity to adopt NEW RULE II to clarify the conditions under which an institutional pharmacy is allowed to operate. See also the statement of reasonable necessity for NEW RULE I.

NEW RULE III ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS (1) During times that an institutional pharmacy does not have a pharmacist in attendance, arrangements must be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel by use of night cabinets, floor stock and, in emergency circumstances, by access to the pharmacy. A pharmacist must be available by phone for consultation during all absences.

(2) If night cabinets are used to store drugs in the absence of a pharmacist, they must be locked and sufficiently secure to deny access to unauthorized persons, and must be located outside of the pharmacy area. Only specifically authorized personnel may obtain access by key or combination, pursuant to a valid prescription order. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the facility, develop inventory listings of drugs included in these cabinet(s), determine who may have access, and shall ensure that:

(a) written policies and procedures are established to implement the requirements of this rule;

(b) all drugs are properly labeled; and

(c) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements.

(3) Whenever access to the cabinet occurs, all of the following information must be recorded on or attached to a suitable form:

(a) a copy of the written practitioner’s orders, showing the date and time the order was issued;

(b) identification of patient;

(c) identification of the patient's room number, if applicable;

(d) the name, strength and quantity of drug removed; and

(e) the signature of the person removing the drug(s).

(4) A complete verification audit of all orders and activity concerning the night cabinet must be conducted by the pharmacist-in-charge or the designee of that pharmacist within 24 hours of the drugs having been removed from the night cabinet.

(5) Whenever any drug is not available from floor stock or night cabinets, and that drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy by a supervisory registered nurse in accordance with established policies and procedures. The responsible nurse shall be designated by the appropriate committee of the institutional facility.

(a) Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing the following information:

(i) patient name;

(ii) the patient's room number if applicable;

(iii) the name, strength and quantity of drug removed;

(iv) the date and time the drug was removed; and

(v) the signature of the nurse removing the drug.

(b) The form shall be sequestered in the pharmacy with the container from which the drug was removed, and a copy of the original drug order.

(6) A copy of the original drug order with the NDC number or other identifying code of the drug(s) provided may be faxed to the pharmacist. A patient profile containing the patient's name, location, allergies, current medication regimen and relevant laboratory values must be prospectively reviewed.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The Board has determined that there is reasonable necessity to adopt NEW RULE III to clarify the conditions under which a night box or pharmacy access may be used in an institutional setting when a pharmacist in not available. See also the statement of reasonable necessity for NEW RULE I.

NEW RULE IV USE OF EMERGENCY DRUG KITS IN CERTAIN INSTITUTIONAL FACILITIES (1) In an institutional facility that does not have an in-house pharmacy, drugs may be provided for use by authorized personnel through emergency kits prepared by the registered pharmacist providing pharmaceutical services to the facility. Such emergency drug kits must meet all of the following requirements:

(a) a registered pharmacist shall prepare and seal the kit;

(b) the supplying pharmacist and the staff physician or appropriate committee of the institutional facility shall jointly determine the identity and quantity of drugs to be included in the kit;

(c) the kit must be locked and stored in a secure area to prevent unauthorized access and to ensure a proper storage environment for the drugs contained therein;

(d) all drugs in the kit must be properly labeled, including lot number and expiration date, and shall possess any additional information that may be required to prevent risk of harm to the patient;

(e) the exterior of the kit must be clearly labeled to indicate:

(i) its use and expiration date of its contents;

(ii) the name, address and telephone number of the supplying pharmacist; and

(iii) a statement indicating that the kit is to be used in emergency situations only pursuant to a valid drug order.

(2) Drugs shall be removed from emergency kits only by the supplying pharmacist or by authorized personnel pursuant to a valid drug order.

(3) The supplying pharmacist shall be notified of any entry into the kit within 24 hours of its occurrence. The supplying pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.

(4) The expiration date of a kit must be the earliest date of expiration of any drug supplied in the kit. On or before the expiration date, the supplying pharmacist shall replace the expired drug.

(5) The supplying pharmacist shall, in conjunction with the appropriate institutional committee, be responsible for development of policies and procedures for safe and appropriate use and maintenance of emergency drug kits.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The Board has determined that there is reasonable necessity to adopt NEW RULE IV to clarify the conditions under which an emergency drug kit may be used in an institutional facility setting. See also the statement of reasonable necessity for NEW RULE I.

NEW RULE V DRUG DISTRIBUTION AND CONTROL (1) The pharmacist-in-charge shall establish written policies and procedures for the safe and efficient distribution of drugs and provision of pharmaceutical care, including the mechanism by which prospective drug review will be accomplished. A current copy of such procedures must be on hand for inspection by the board of pharmacy.

(2) Automated dispensing devices must be stocked with drugs only by or under the supervision of a registered pharmacist. At the time of removal of any drug, the device must automatically make an electronic record indicating the date of removal, the name, strength, and quantity of drug removed, name of the patient for whom the drug was ordered, and the name or other identification of the person removing the drug. These records must be maintained for a period of two years.

(3) Drugs or herbal/alternative food supplement products brought into an institutional facility by a patient must not be administered unless they can be identified and their quality assured by a pharmacist, and their use has been authorized by the attending physician. If such drugs are not to be administered, the pharmacist-in-charge shall develop policies and procedures for storing them for return to the patient upon discharge or transferring them to an adult member of the patient's immediate family.

(4) Investigational drugs must be stored in and dispensed from the pharmacy only pursuant to written policies and procedures. Complete information regarding these drugs and their disposition must be maintained in the pharmacy. The drug monograph and a signed patient consent form must be obtained and made available in accordance with federal guidelines.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, MCA

REASON: The Board has determined that there is reasonable necessity to adopt NEW RULE V to clarify drug distribution and storage in an institutional facility setting. See also the statement of reasonable necessity for NEW RULE I.

NEW RULE VI INSTITUTIONAL PHARMACIST AND PHARMACIST-IN-CHARGE RESPONSIBILITY (1) The pharmacy director/pharmacist-in-charge shall provide for applicable policies and procedures to ensure:

(a) mechanisms for receiving and verifying drug orders from prescribers and evaluating them for safety and therapeutic appropriateness based on patient parameters and dosing guidelines;

(b) appropriate filling and proper labeling of all containers from which drugs are to be dispensed or administered on an inpatient or outpatient basis;

(c) a system for the admixture of parenteral products accomplished within the pharmacy, and verification that the facility's department of nursing will provide education and training of nursing personnel regarding sterile technique, stability and compatibility of parenteral products not mixed within the pharmacy;

(d) appropriate clinical services and monitoring of outcomes, and the development of new areas of pharmaceutical care appropriate for that institution;

(e) a mechanism by which changes in a patient's medication regimen are conveyed to that patient's home pharmacy;

(f) maintaining and distributing a list of emergency drugs, antidotes, and their doses throughout the institution;

(g) pharmacy participation in formulary development;

(h) participation in drug utilization review and monitoring of adverse drug reactions and development of procedures to avoid problems identified;

(i) evaluation of reported medication errors and development of procedures to prevent those errors;

(j) proper acquisition and secure, temperature-controlled storage of all prescription drugs;

(k) quality control of sterile and non-sterile pharmaceutical products, including procedures for identifying, removing and destroying outdated products;

(l) pharmacy safety and security;

(m) utilization of registered technicians or technicians in training;

(n) accurate distribution systems and secure, temperature-controlled storage of pharmaceutical products throughout the institution;

(o) unit-dosing of bulk pharmaceuticals, compounding and sterilization of drug products if applicable;

(p) the appropriate use, security and accountability of controlled substances;

(q) staff development and competency evaluation;

(r) maintenance of all required records; and

(s) compliance with all other requirements of the Montana board of pharmacy.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, MCA

REASON: The Board has determined that there is reasonable necessity to adopt NEW RULE VI to clarify the conditions and procedures under which an institutional pharmacy is required to operate. See also the statement of reasonable necessity for NEW RULE I.

NEW RULE VII STERILE PRODUCTS (1) Policies and procedures must be prepared for the compounding, dispensing, delivery, administration, storage and use of sterile pharmaceutical products. The policies must include a quality assurance program for monitoring personnel qualifications and training in sterile technique, product storage, stability standards, and infection control. Policies and procedures must be current and available for inspection by a designee of the board of pharmacy.

(2) An institutional pharmacy compounding sterile products must have an area restricted to entry by authorized personnel. That area must be designed to avoid unnecessary traffic and airflow disturbances.

(3) An institutional pharmacy compounding sterile products must utilize an appropriate aseptic environmental control device such as a laminar flow biological safety cabinet capable of maintaining Class 100 conditions during normal activity.

(4) Cytotoxic drugs must be prepared in a vertical flow Class II biological safety cabinet. Non-cytotoxic sterile pharmaceuticals must not be compounded in this cabinet.

(a) Protective apparel including non-vinyl gloves, gowns and masks must be available, and gloves must be worn at all times.

(b) Appropriate containment techniques must be used in addition to aseptic techniques required for sterile product preparation.

(c) Prepared doses of cytotoxic drugs must be clearly identified, labeled with proper precautions and dispensed in a manner to minimize risk of cytotoxic spills.

(d) Disposal of cytotoxic waste must comply with all applicable local, state and federal laws.

(e) Written procedures for handling cytotoxic spills must be included in the policies and procedures manual.

(5) All parenteral admixtures must be labeled with date of preparation and expiration date clearly indicated, patient name and room number, name and strength and/or amount of drug and base solution, and any special handling or storage instructions.

(6) All aseptic environmental control devices must be certified by an independent contractor for operational efficiency at least every 12 months or when relocated,

according to federal standard 209E. Pre-filters must be inspected periodically and replaced if needed.

(7) Inspection and replacement dates must be documented and maintained for a period of at least two years.

(8) Documented records of ongoing quality assurance programs, justification of expiration dates chosen, and employee training records and technique audits must be available for inspection by the board of pharmacy.

AUTH: 37-7-201, MCA
IMP: 37-7-201, 37-7-307, 37-7-308, MCA

REASON: The Board has determined that there is reasonable necessity to adopt NEW RULE VII to clarify the conditions under which an institutional pharmacy must operate with respect to sterile products controlled by the pharmacy. See also the statement of reasonable necessity for NEW RULE I.

NEW RULE VIII RETURN OF MEDICATION FROM LONG TERM CARE FACILITIES -- DONATED DRUG PROGRAM (1) In facilities licensed by the Montana department of health and human services where United States pharmacopeia storage requirements are assured, unit-dosed legend drugs, with the exception of controlled substances, no longer needed by the patient for whom they were prescribed, may be transferred to a provisional permitted pharmacy for relabeling and dispensing free of charge to patients who are uninsured, indigent or have insufficient funds to obtain needed prescription drugs. Prescription medications may be dispensed pursuant to a valid prescription order. A usual and customary dispensing fee may be charged at the pharmacist's discretion.

(2) The pharmacist-in-charge of the provisional permitted pharmacy shall be responsible for determining the suitability of the legend drug for use. Medications must be unopened in sealed, unaltered unit dose containers that meet USP standards for light, moisture and air permeation. No product in which drug integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.

(3) A re-dispensed prescription medication must be assigned the expiration date stated on the unit dose packaging. Medications packaged in unit dose form within a pharmacy must be given an expiration date of one year or actual date of expiration of the medication, whichever comes first, and must not be repackaged.

(4) No medication can be redistributed more than once.

(5) Only authorized personnel shall carry out the physical transfer of medication in either facility, pursuant to established policies and procedures.

(6) The patient's name and other identifying marks must be obliterated from packaging prior to transfer. The drug name, strength, lot number and expiration date must remain clearly visible on the packaging.

(7) An inventory list of drugs transferred, including expiration dates, must accompany the drugs, and must be

maintained in the provisional permitted pharmacy for a period of two years.

(8) Policies and procedures to document safe storage and transfer of unneeded medications must be written and adhered to by the facilities involved, and must be available for inspection by an authorized representative of the Montana board of pharmacy or public health and human services.

AUTH: 37-7-201, 37-7-1401, MCA
IMP: 37-7-201, 37-7-1401, 37-7-1402, MCA

REASON: The Board has determined that there is reasonable necessity to adopt NEW RULE VIII to implement the provisions of Chapter 362, Laws of 2001 (SB 288). Pursuant to 37-7-1401, MCA, rule-making by the Board is mandatory.

NEW RULE IX PHARMACIST MEAL/REST BREAKS (1) In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break for a period of up to 30 minutes per shift without closing the pharmacy and removing support personnel, provided the pharmacist reasonably believes that the security of prescription drugs will be maintained in the pharmacist's absence.

(2) The time of closure and re-opening will be conspicuously posted in clear view of patients approaching the prescription area and will be consistently scheduled.

(3) In the pharmacist's absence a sign indicating that no pharmacist is on duty will be conspicuously displayed in clear view of patients approaching the prescription area.

(4) The pharmacist will remain on the premises if the prescription area is to remain open, and be available for emergencies.

(5) When authorized by the pharmacist, only registered technicians directly involved in the process of filling prescriptions may remain in the prescription department to perform non-discretionary duties as delineated by the pharmacist.

(6) Upon returning, the pharmacist shall review any work performed in the pharmacist's absence.

(7) In the pharmacist's absence there may be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor may counseling be provided.

(8) At the discretion of the pharmacist, previously checked medication refills may be handed to patients or their agents by registered technicians in the pharmacist's absence, and the technicians must offer the patient counseling by the pharmacist. If the patient desires counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon return.

(9) Telephoned new prescriptions must not be accepted by support personnel in the pharmacist's absence.

(10) New hardcopy prescriptions may be accepted and processed by registered technicians in the pharmacist's

absence. These prescriptions may not be dispensed until the pharmacist has performed drug utilization review and completed the final check.

(11) If two or more pharmacists are on duty, the pharmacists shall stagger their breaks so that the prescription department is not left without a pharmacist on duty.

(12) The pharmacist-in-charge shall develop written policies and procedures for operation of the prescription department in the temporary absence of the pharmacist.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

REASON: The Board has determined in order to protect the public health and safety of those persons who use prescription drugs, and the health and safety of individuals near such persons, there is reasonable necessity to adopt proposed NEW RULE IX. The Board has been made aware of situations where a pharmacist has been expected to work an entire shift without a rest or meal break. The Board, in its judgment, believes that a maximum of a 30 minute rest or meal break is necessary to help avoid errors arising from too many hours of uninterrupted work, as balanced against the problem of not providing access to the pharmacy when the pharmacist is on a break.

5. ARM 24.174.302, 24.174.810, 24.174.811, and 24.174.812, the rules proposed to be repealed, are as follows:

24.174.302 HOSPITAL/HEALTH CARE FACILITY DEFINITIONS is found at ARM page 24-19522.

AUTH: 37-7-201, MCA
IMP: 37-7-321, MCA

REASON: The Board has determined that the proposed repeal is reasonably necessary as part of the revision and clarification of rules related to institutional pharmacies, and to coordinate with the proposed adoption of NEW RULES I through VII.

24.174.810 CLASS I FACILITY is found at ARM pages 24-19669 through 24-19671.

AUTH: 37-7-201, MCA
IMP: 37-7-201(2), 37-7-321(2), MCA

REASON: The Board has determined that the proposed repeal is reasonably necessary as part of the revision and clarification of rules related to institutional pharmacies, and to coordinate with the proposed adoption of NEW RULES I through VII.

24.174.811 CLASS II FACILITY is found at ARM page 24-19671.

AUTH: 37-7-201, MCA
IMP: 37-7-201(2), 37-7-321(2), MCA

REASON: The Board has determined that the proposed repeal is reasonably necessary as part of the revision and clarification of rules related to institutional pharmacies, and to coordinate with the proposed adoption of NEW RULES I through VII.

24.174.812 CLASS III FACILITY is found at ARM page 24-19672.

AUTH: 37-7-201, MCA
IMP: 37-7-201(2), 37-7-321(2), MCA

REASON: The Board has determined that the proposed repeal is reasonably necessary as part of the revision and clarification of rules related to institutional pharmacies, and to coordinate with the proposed adoption of NEW RULES I through VII.

6. Concerned persons may present their data, views or arguments either orally or in writing at the hearing. Written data, views or arguments may also be submitted to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, by facsimile to (406) 841-2343, or by e-mail to dlibbsdpha@state.mt.us and must be received no later than 5:00 p.m., August 9, 2002.

7. An electronic copy of this Notice of Public Hearing is available through the Department's site on the World Wide Web at http://discoveringmontana.com/dli/bsd under the rule notice section for the Board of Pharmacy. The Department strives to make the electronic copy of this Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered.

8. The Board of Pharmacy maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this Board. Persons who wish to have their name added to the list shall make a written request to the board which includes the name and mailing address of the person to receive notices and specifies that the person wishes to receive notices regarding all Board of Pharmacy administrative rulemaking or other administrative proceedings. Such written request may be mailed or delivered to the Board of Pharmacy, 301 South Park Avenue, P.O. Box 200513, Helena, Montana 59620-0513, faxed to the office at (406) 841-2343, e-mailed to dlibsdpha@state.mt.us or may be made by completing a request form at any rules hearing held by the agency.

9. The Board of Pharmacy will meet at 8:00 a.m., August 29, 2002, to consider the comments made by the public, the proposed responses to those comments, and take final action on the proposed amendments and new rules. The meeting will be held by teleconference. Members of the public are welcome to come to the Board's offices in Helena and listen to the Board's deliberations, but the Board cannot accept any comments concerning the proposed amendments, new rules and repeals beyond the August 9, 2002, deadline.

10. The bill sponsor notice requirements of 2-4-302, MCA, apply and have been fulfilled.

11. Jack Atkins, attorney, has been designated to preside over and conduct this hearing.

BOARD OF PHARMACY
ALBERT A.FISHER, R.Ph.,
PRESIDENT

By: /s/ KEVIN BRAUN
Kevin Braun
Rule Reviewer

By: /s/ WENDY J. KEATING
Wendy J. Keating, Commissioner
DEPARTMENT OF LABOR & INDUSTRY

Certified to the Secretary of State, July 1, 2002.